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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,526	01/29/2001	Keith Myers	3FTHERA.007A	9761

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

BARRETT, THOMAS C

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/772,526

Applicant(s)

MYERS ET AL.

Examiner

Thomas C. Barrett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-32 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-12, 16-21, 23, 24, 33-54, 56 and 59-63 is/are rejected.
- 7) ☒ Claim(s) 8, 25, 55, 57 and 58 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 4, 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Species XII in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13 and 22 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

Furthermore claims 14 and 15 are withdrawn by the Examiner as being drawn to a nonelected species, there being no allowable generic or linking claim.

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

The abstract of the disclosure is objected to because of undue length. Correction is required. See MPEP § 608.01(b).

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

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requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the corresponding leaflet" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the line adjacent the out-flow edges of the leaflets" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-12, 16-17, 23-24, 39-54 and 56 rejected under 35 U.S.C. 102(b) as being anticipated by Peredo (6,254,636 B1). Peredo discloses a prosthetic semilunar heart valve comprising a plurality of substantially identical leaflets (11) having tabs (18) extending outwards from the side edge and beyond the out-flow edge of the leaflets (Fig. 4) and further comprising a scalloped in-flow edge (14) and scalloped out-flow edge in a plane perpendicular to the axis of the stent (Fig. 8). The tab portions of adjacent leaflets are connected to one another by reinforcement material (22) to form commissural attachment tabs that extend beyond the out-flow end of the valve (Fig. 7). The leaflets can be made of equine pericardium (col.3, lines 36-48).

Claims 16, 18-19, 20-21, 23, 33, 38, 59-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Ionescu et al. (4,388,735). Ionescu et al. discloses a prosthetic valve comprising leaflets sewn together in a facing relationship a scalloped annulus and outlet portion (Fig. 6) with three commissural attachment locations (Fig. 7), a cloth reinforcement member (220) and tabs. Side edges are interpreted as where the sides first meet and the tabs are where the leaflets overlap.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ionescu et al. (4,388,735) in view of Love et al. (5,163,955) as cited in Applicant's IDS. Ionescu et al. discloses a prosthetic valve comprising leaflets however Ionescu et al. fails to disclose the leaflets as being laser cut pericardium. Love et al. teaches the use of laser cut pericardium, which can be computer controlled and therefore more precision (col. 24, lines 15-30). It would have been obvious to one of ordinary skill in the art to combine the teaching of use of laser cut pericardium, as taught by Love et al., to a prosthetic valve comprising leaflets as per Ionescu et al., in order to have computer controlled cuts and therefore more precision.

Claims 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ionescu et al. (4,388,735) in view of Peredo (6,254,636 B1). Ionescu et al. discloses a prosthetic valve comprising leaflets however Ionescu et al. fails to disclose the leaflets as being equine pericardium. Peredo teaches the use of equine pericardium (col.3, lines 36-48), which is widely available and lower in cost. It would have been obvious to one of ordinary skill in the art to combine the teaching of use of equine pericardium, as taught by Peredo, to a prosthetic valve comprising leaflets as per Ionescu et al., because of its availability and lower cost.

Allowable Subject Matter

Claims 8, 25, 55 and 57-58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Claims 26-32 are allowed over prior art of record. The prior art does not teach or make obvious a stentless heart valve comprising a leaflet with a longitudinal slot in a tab that interlocks with the tab of another leaflet in the manner of the presently claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (703) 308-8295. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703) 308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3580 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0850.



Thomas Barrett
February 24, 2003



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700